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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.
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09/122,427 07/24/98 ZOU

Y UTSC584/G00

HM42/1124

EXAMINER

KENNETH D GOODMAN
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KITSHORE, G

ART UNIT

PAPER NUMBER

1615

DATE MAILED:

11/24/98

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This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

Responsive to communication(s) filed on _____
 This action is FINAL.
 Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 30 days month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

Claim(s) 1-29 & 32 -51 is/are pending in the application.
Of the above, claim(s) _____ is/are withdrawn from consideration.
 Claim(s) _____ is/are allowed.
 Claim(s) _____ is/are rejected.
 Claim(s) _____ is/are objected to.
 Claims 1-29 & 32 -51 are subject to restriction or election requirement.

Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
 The drawing(s) filed on _____ is/are objected to by the Examiner.
 The proposed drawing correction, filed on _____ is approved disapproved.
 The specification is objected to by the Examiner.
 The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
 All Some* None of the CERTIFIED copies of the priority documents have been
received.
 received in Application No. (Series Code/Serial Number) _____
 received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

Notice of Reference Cited, PTO-892
 Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
 Interview Summary, PTO-413
 Notice of Draftsperson's Patent Drawing Review, PTO-948
 Notice of Informal Patent Application, PTO-152

- SEE OFFICE ACTION ON THE FOLLOWING PAGES -

DETAILED ACTION

Election/Restriction

1. **Restriction to one of the following inventions is required under 35 U.S.C. 121:**
 - I. **Claims 1-9 are, drawn to an aqueous/t-butanol solvent system/lyophilized powder, classified in class 428, subclass 402.2.**
 - II. **Claims 32-40 and 51 are, drawn to aqueous/t-butanol solvent system/lyophilized powder containing either an anthracyclin or annamycin or an active agent, classified in class 424, subclass 489.**
 - III. **Claims 41-47, 48-49 are, drawn to methods of preparation of anthracyclin (claims 41-48) or annamycin (48-49) containing aqueous/t-butanol solvent system/lyophilized powder, classified in class 264, subclass 4.1.**
 - IV. **Claims 19-22 are, drawn to a sterically, antigenicity hindered liposome, classified in class 428, subclass 402.2.**
 - V. **Claims 23-29 and 50 are, drawn to a pharmaceutical composition containing anthracyclins and method of inhibiting tumors, classified in class 424, subclass 450.**
 - VI. **Claim 10-17 and 18 are, drawn to methods of preparation of anthracyclin or annamycin containing liposomes, classified in class 264, subclass 4.1.**

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2. The inventions are distinct, each from the other because of the following reasons:

Inventions I or II and IV or V are related as mutually exclusive species in an intermediate-final product relationship. Distinctness is proven for claims in this relationship if the intermediate product is useful to make other than the final product (MPEP § 806.04(b), 3rd paragraph), and the species are patentably distinct (MPEP § 806.04(h)). In the instant case, the intermediate product is deemed to be useful to make either empty liposomes or liposomes containing any active agent or anthracyclins as applicants themselves are claiming and the inventions are deemed patentably distinct since there is nothing on this record to show them to be obvious variants. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions anticipated by the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

3. Inventions V and VI are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the process can be used to encapsulate active agents other

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than anthracyclins or cosmetics; or the product can be made by classical methods of preparation of liposomes which include drying the lipid and hydrating the lipid film.

4. Inventions II and III are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the process can be used to incorporate active agents other than anthracyclins or annamycin or even cosmetics.

Groups I and II are independent and distinct in that I is directed to a powder without active agents and II is directed to powders with anthracyclin or annamycin.

Groups IV and V are independent and distinct in that IV is directed to a empty liposomes without active agents and V is directed to liposomes with anthracyclin or annamycin.

Inventions III and VI are independent and distinct in that they are different processes oriented to prepare different preparations.

5. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

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6. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to *G.S. Kishore* whose telephone number is (703) 308-2440.

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The examiner can normally be reached on Monday-Thursday from 6:30 A.M. to 4:00 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, T.K. Page, can be reached on (703)308-2927. The fax phone number for this Group is (703)305-3592.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [thurman.page@uspto.gov].

All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

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Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703)308-1235.



Gollamudi S. Kishore, Ph. D

Primary Examiner

Group 1600

gsk

November 20, 1998